894

(29)

No. 05-1382

FILED
SEP 20 2006
OFFICE OF THE CLERK
SUPREME COURT, U.S.

IN THE

Supreme Court of the United States

ALBERTO R. GONZALES, ATTORNEY GENERAL,
Petitioner,

v.

PLANNED PARENTHOOD FEDERATION OF AMERICA, INC., *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF *AMICI CURIAE* AMERICAN MEDICAL WOMEN'S ASSOCIATION, AMERICAN PUBLIC HEALTH ASSOCIATION, ET AL. IN SUPPORT OF RESPONDENTS

LORIE A. CHAITEN*
LEAH BARTELT
ROGER BALDWIN FOUNDATION
AMERICAN CIVIL LIBERTIES
UNION OF ILLINOIS
180 N. Michigan Ave.,
Suite 2300
Chicago, IL 60601
(312) 201-9740

CARTER G. PHILLIPS
EAMON P. JOYCE
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000

ROBERT N. HOCHMAN
SIDLEY AUSTIN LLP
One South Dearborn Street
Chicago, IL 60603
(312) 853-2936

Counsel for Amici Curiae

* Counsel of Record

September 20, 2006

[Additional *Amici Curiae* Listed on Inside Cover]

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D.C. 20001

This brief is filed on behalf of the following seven organizations and forty-one individuals:

American Medical Women's Association
American Public Health Association
Medical Students for Choice
National Family Planning & Reproductive Health Association
New York Obstetrical Society
Physicians for Reproductive Choice
University of Chicago Hospitals, Department of Obstetrics and Gynecology
David B. Bingham, M.D.
Robert L. Blake Jr, M.D.
Debra E. Bright, M.D.
Herbert P. Brown, M.D.
J. Douglas Butler, D.P.M.
Paula M. Castano, M.D.
Dennis D. Christensen, M.D.
Arnold W. Cohen, M.D.
Anne Davis, M.D.
James W. Frederiksen, M.D.
Eugene Glick, M.D.
Matthew C. Gomillion, M.D.
Stephanie Robin Goodman, M.D.
W. Benson Harer Jr., M.D.
Paula J. Adams Hillard, M.D.
Steven Hockstein, M.D.
Deborah E. Klein, M.D.
Carla Shyrl Lupi, M.D.
Margot Kushel, M.D.
Ruth Fainberg Lesnewski, M.D.
David Magnus, Ph.D.
David R. Mehr, M.D., M.S.
Jon F. Merz, M.B.A., J.D., Ph.D.
Caroline Mitchell, M.D.
Elizabeth Pirruccello Newhall, M.D.
Malkah T. Notman, M.D.
Deborah Oyer, M.D.
Susan M. Reverby, Ph.D.
Jed S. Rosen, M.D.
David Rosner, Ph.D.
Lanie Friedman Ross, M.D., Ph.D.
Irene N. Sills, M.D.
Richard Smiley, M.D., Ph.D.
Bruce S. Steir, M.D.
Catherine Susan Stika, M.D.
Nada Logan Stotland, M.D., M.P.H.
Debra Stulberg, M.D.
Gina S. Sucato, M.D., M.P.H.
Albert G. Thomas, M.D.
Katharine O'Connell White, M.D.
Paul Root Wolpe, Ph.D.

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	iii
INTEREST OF *AMICI CURIAE*	1
SUMMARY OF ARGUMENT	2
ARGUMENT	4
I. INTACT D&E HAS EVOLVED IN A MANNER CONSISTENT WITH OTHER SURGICAL TECHNIQUES AND ITS SAFETY AND HEALTH BENEFITS HAVE BEEN EQUALLY WELL DEMONSTRATED	4
A. Contrary To Congress's Findings, Surgical Techniques Develop Without Reliance On Controlled Trials	4
B. The Evolution Of Intact D&E Comports With The Standards For Safety And Efficacy In Surgical Advancement	12
II. THE HEALTH BENEFITS OF INTACT D&E MANDATE THAT IT BE CONSTITUTIONALLY PROTECTED	18
A. Women's Health Is Primary To, If Not Dispositive Of, The Constitutional Analysis	20
B. Banning An Intact Approach To D&E Denies Women A Potential Health Benefit By Increasing The Health Risks They Face	22
III. ADOPTING THE GOVERNMENT'S POSITION WOULD MARK A SEA CHANGE IN THIS COURT'S ABORTION JURISPRUDENCE	26

TABLE OF CONTENTS—continued

Page

A. This Court Should Reject The Claim That Preventing Abortion Which "Resembles Infanticide" Is A Compelling Interest Sufficiently Strong To Overcome Women's Interest In Access To The Safest Abortion Procedure 26

B. This Court Rightly Has Never Held That A Restriction On Abortion May Survive Even Though It Would Increase Risks To Women 29

CONCLUSION 30

TABLE OF AUTHORITIES

CASES Page

Anderson v. *Weinsweig*, 34 Fed. Appx. 916 (4th Cir. 2002) 24
Ashcroft v. *Free Speech Coal.*, 535 U.S. 234 (2002) 27, 28
Ayotte v. *Planned Parenthood*, 126 S. Ct. 961 (2006) 20
City of Akron v. *Akron Ctr. for Reprod. Health, Inc.*, 462 U.S. 416 (1983), *overruled on other grounds by Planned Parenthood* v. *Casey*, 505 U.S. 833 (1992) 18, 19, 20, 21, 25
Colautti v. *Franklin*, 439 U.S. 379 (1979) 20
Dent v. *W. Virginia*, 129 U.S. 114 (1889) 25
Fulton v. *Loucks*, 947 F.2d 944 (6th Cir. 1991) 24
Lawrence v. *Texas*, 539 U.S. 558 (2003) 28
Nat'l Abortion Fed'n v. *Ashcroft*, 330 F. Supp. 2d 436 (S.D.N.Y. 2004), *aff'd in part sub nom.* 437 F.3d 278 (2d Cir. 2006) 14
Nat'l Abortion Fed'n v. *Gonzales*, 437 F.3d 278 (2d Cir. 2006) 22
Planned Parenthood v. *Danforth*, 428 U.S. 52 (1976) 19, 20
Planned Parenthood v. *Casey*, 505 U.S. 833 (1992) 19, 20, 21
Planned Parenthood v. *Doyle*, 162 F.3d 463 (7th Cir. 1998) 22
Planned Parenthood Ass'n v. *Ashcroft*, 462 U.S. 476 (1983) 25
Romer v. *Evans*, 517 U.S. 620 (1996) 28, 29
Saenz v. *Roe*, 526 U.S. 489 (1999) 29
Simopoulos v. *Virginia*, 462 U.S. 506 (1983) 19
Stenberg v. *Carhart*, 530 U.S. 914 (2000) ..... *passim*

TABLE OF AUTHORITIES—continued

Page

Thornburg v. *Am. Coll. of Obstetricians & Gynecologists*, 476 U.S. 747 (1986), *overruled by Planned Parenthood* v. *Casey*, 505 U.S. 833 (1992) 20

United States Dep't of Agric. v. *Moreno*, 413 U.S. 528 (1973) 29

United States v. *Rutherford*, 442 U.S. 544 (1979) 23

STATUTE

Partial Birth Abortion Ban Act of 2003, Pub. L. No. 108-105, 117 Stat. 1201 (codified at 18 U.S.C. § 1531) 2

SCHOLARLY AUTHORITIES

Abortion Surveillance–United States 2002, 54 Morbidity & Mortality Weekly Report (Centers for Disease Control & Prevention), Nov. 25, 2005 17

ACOG, *Ethics in Obstetrics and Gynecology* (2d ed.) 25

ACOG Statement of Policy (Jan. 1997, *reaff'd*, Sept. 2000, *reaff'd*, July 2004) 16

Gallstones and Laparoscopic Cholecystectomy, NIH Consensus Statement 10(3) (Sept. 16, 1992), *available at* http://consensus.nih.gov/1992/1992GallstonesLaparoscopy090html.htm .. 12

Claus Bartels et al., *Cardiopulmonary Bypass: Evidence or Experience Based?*, 124 J. Thorac. Cardiovasc. Surg. 2 (2002) 6, 7

Tom L. Beauchamp & James F. Childress, *Principles of Biomedical Ethics* 327 (5th ed. 2001) 7, 8, 23, 25

TABLE OF AUTHORITIES—continued

Page

Kjell Benson et al., *A Comparison of Observational Studies and Randomized, Controlled Trials*, 342 New Eng. J. Med. 1878 (2000) 7

Stephen T. Chasen, *Surgical Abortion in the Second Trimester*, Presentation at NAF Risk Management Conference (Oct. 2004) 16

Stephen T. Chasen et al., *Dilation and Evacuation at ≥ 20 Weeks: Comparison of Operative Techniques*, 190 Am. J. Obstet. & Gynec. 1180 (2004) 8, 14, 16, 17

Stephen T. Chasen et al., *Obstetric Outcomes After Surgical Abortion at ≥ 20 Weeks' Gestation*, 193 Am. J. Obstet. Gynec. 1161 (2005) 16

Thomas L. Dent et al., *Minimal Access General Surgery: the Dawn of a New Era*, 161 Am. J. Surg. 323 (1991) 11

Joel E. Frader & Donna A. Caniano, *Research and Innovation in Surgery, in Surgical Ethics* 216 (Laurence B. McCullough et al. eds., 1998) 9

Benjamin Freedman, *Equipoise and the Ethics of Clinical Research*, 317 New Eng. J. Med. 141 (1987) 7

William H. Frist & D. Craig Miller, *Repair of Ascending Aortic Aneurisms and Dissections*, 1 J. Cardiac Surg. 33 (1986) 5

Eric K. Fung, et al., *Randomized Controlled Trials for Evaluating Surgical Questions*, 128 Arch. Otolaryagol. Head Neck Surg. 631 (2002) 6, 7, 8, 9

Thomas R. Gadacz et al., *Traditional Versus Laparoscopic Cholecystectomy*, 161 Am. J. Surg. 336 (1991) 11

TABLE OF AUTHORITIES—continued

Page

U. Giger et al., *Laparoscopic Cholecystectomy in Acute Cholecystitis: Indication, Technique, Risk and Outcome*, 390 Langenbecks Arch. Surg. 373 (2005) 10, 11

D. A. Grimes et al., *Mifepristone and misoprostal versus dilation and evacuation for mid-trimester abortion: a pilot randomized controlled trial*, 111 B. J. Obstet. Gynecol. 148 (2004) 8

David A. Grimes, *Estimation of Pregnancy-Related Mortality Risk by Pregnancy Outcome, United States, 1991-1999*, 194 Am. J. Obstet. & Gynec. 92 (2006) 23

Martin Haskell, *Dilation and Extraction for Late Second Trimester Abortion*, Presentation at National Abortion Fed'n, Second Trimester Abortion: From Every Angle Seminar (Sept. 13, 1992) 15

W. Martin Haskell et al., *Surgical Abortion After the First Trimester, in A Clinicians Guide to Medical & Surgical Abortion* 123 (Maureen Paul et al. eds., 1999) 13, 14, 15, 16

David S. Jones, *Visions of Cure: Visualization, Clinical Trials, and Controversies in Cardiac Therapies, 1968-1998*, 91 Isis 504 (2002) 9, 12

Albert R. Jonsen et al., *Clinical Ethics* (6th ed. 2006) 7

R. Lefering & E. Neugebauer, *Problems of Randomized Controlled Trials (RCT) in Surgery* (1997), *available at* http://www.symposion.com/nrccs/lefering.htm 8, 9, 11, 12

G.S. Litynski & V. Paolucci, *Origin of Laparoscopy: Coincidence of Surgical Interdisciplinary Thought?*, 22 World J. Surg. 899 (1998) 10

TABLE OF AUTHORITIES—continued

Page

Bernard Lo, *Resolving Ethical Dilemmas: A Guide for Clinicians* (3d ed. 2005) 7, 8

J. Barry McKernan, *Origin of Laparoscopic Cholecystectomy in the USA: Personal Experience*, 23 World J. Surg. 332 (1999) 11

James T. McMahon, *Intact D&E: The First Decade* (presented at NAF conference, Apr. 2, 1995) 15

Robin S. McLeod, *Issues in Surgical Randomized Controlled Trials*, 23 World J. Surg. 1210 (1999) 6, 7, 9

Sherwin B. Nuland, *Doctors: The Biography of Medicine* (1988) 5

Michael J. Solomon & Robin S. McLeod, *Surgery and the Randomised Controlled Trial: Past, Present and Future*, 169 Med. J. Australia 380 (1998) 7, 8

Phillip G. Stubblefield et al., *Methods for Induced Abortion*, 104 Obstet. & Gynec. 174 (2004) 13, 14

C. Randle Voyles, *A Practical Approach to Laparoscopic Cholecystectomy*, 161 Am. J. Surg. 365 (1991) 11, 16

OTHER AUTHORITIES

Oxford English Dictionary (2d ed. 1989) 26

American Heritage Dictionary (4th ed. 2000) 26

INTEREST OF *AMICI CURIAE*

Amici curiae are medical and public health organizations and institutions, as well as individual physicians and academicians who oppose the Partial Birth Abortion Act of 2003 because it jeopardizes women's health by criminalizing safe and effective abortion procedures, and further restricts the study and advancement of such procedures. *Amici* and their members believe that their insight and hands-on experience with the methods by which surgical procedures evolve and surgeons determine whether procedures are safe and beneficial for their patients will assist the Court in construing Congress's findings and the impact of the statute in this case.

Amici include 41 individual physicians, surgeons, medical ethicists, medical historians and the following entities: **American Medical Women's Association** (national organization of 10,000 women physicians, surgeons, and physicians-in-training dedicated to promoting women's health); **American Public Health Association** (oldest, largest, and most diverse organization of public health professionals in the world; has a long standing commitment to reproductive rights and reproductive choice); **Medical Students for Choice** (organization of nearly 10,000 medical students and residents seeking comprehensive medical education including abortion training); **National Family Planning & Reproductive Health Association** (represents clinicians, administrators, researchers, educators, advocates and providers in the family planning field who provide reproductive health care services at nearly 4,500 clinics to more than 5 million women annually); **New York Obstetrical Society** (a 140-year-old regional organization of obstetrician-gynecologists and gynecological surgeons who are leaders in the field of women's health care); **Physicians for Reproductive Choice** (national organization of physicians of various specialties that exists to promote,

educate and advocate about the importance of comprehensive reproductive healthcare and to ensure that all people have the knowledge, access to quality services and freedom to make their own reproductive health decisions); **University of Chicago Hospitals, Department of Obstetrics and Gynecology** (physicians and surgeons, including maternal-fetal medicine specialists, practicing at a top ranked hospital, affiliated with a leading academic institution).[1]

SUMMARY OF ARGUMENT

Through the Partial Birth Abortion Ban Act of 2003 (the "Act"), Pub. L. No. 108-105, 117 Stat. 1201 (codified at 18 U.S.C. § 1531), Congress has attempted to prohibit some of the most common and safest methods of abortion in the second trimester, without providing an exception to preserve a woman's health. Congress attempted to justify this attack on women's health by "finding" that so-called "partial birth abortion" is never medically necessary because "[t]here is no credible medical evidence that partial-birth abortions are safe or are safer than other abortion procedures." *Id.* § 2(14)(B), 117 Stat. at 1204.[2] Congress based that conclusion in substantial part on the fact that no controlled or comparative studies or peer-reviewed articles had demonstrated the safety and efficacy of such procedures. See *id.*; but see Br. *Amicus Curiae*, American College of Obstetricians and Gynecologists 17-18 (collecting peer-reviewed literature on intact D&E).

---

[1] Letters of consent have been filed with the Clerk. Pursuant to Rule 37.6, *amici* state that no counsel for a party authored any part of this brief, and no person or entity other than *amici* and their counsel made a monetary contribution to the preparation or submission of this brief.

[2] "[P]artial birth abortion" is not a medical term and does not refer to any procedure. But, since the Government sometimes asserts that it is the same as surgical abortions in which the physician succeeds in removing the fetus intact or largely intact (referred to herein as the intact variation of dilation and evacuation abortion, or "intact D&E"), *amici* address the safety and evolution of intact D&E procedures.

Congress's conclusion is built on a false premise. Controlled or comparative studies are common in the pharmaceutical context, and are certainly a valuable method of evaluating safety and efficacy in medicine in general. However, they have never been the method surgeons have used to determine whether new surgical procedures, or variations on familiar procedures, are safe to employ and provide health benefits to their patients. Surgery, by its nature, does not fit the randomized control trial ("RCT") paradigm. When a new technique is first developed, there is simply no way to create a sufficient number of "trials" to conduct a controlled study. Even after a new surgical technique has reached a level of acceptance in the surgical community, circumstances often continue to preclude such evaluation. However, despite substantial impediments to controlled studies, the level of knowledge and skill in the surgical profession has exploded in the past century because the surgical community has developed a field-specific approach: it engages in widespread communication regarding common problems, theoretical approaches and ultimately practical solutions. When a surgeon finds a technique that represents an improvement over prior techniques, he or she records the results and shares them with others, who then begin to perform the new technique and share their experience.

This is the way numerous now familiar procedures were introduced and evaluated when they were new and untested. The safety and health benefits of intact D&E have been demonstrated in the same manner. Accordingly, as each of the lower courts to have addressed Congress's findings has concluded, "credible medical evidence" does, in fact, exist to show that intact D&E is not only safe and effective, but it is often safer than alternative methods of terminating pregnancy in the second trimester.

When viewed in light of these standards, this Court's longstanding abortion jurisprudence renders the Act

unconstitutional. The Act places women's health in jeopardy. This Court has *never* held that *any* government interest is strong enough to outweigh the combined interest of the state and the woman in her health.

Neither can the Act be saved by the availability of other abortion procedures that the Government claims are "safe enough." This artificial standard of safety is foreign to surgical practice. Surgeons seek to maximize the safety and health benefits for each patient for whom they care. They do not merely conclude that a procedure is "safe enough" and then decline to take further steps or make additional innovations to advance their patients' health interests. Nor would any patient want his or her physician to follow such a minimalist approach. An ongoing effort to reduce patient risk is a paramount obligation for surgeons—an obligation that cannot, consistent with this Court's precedent, be undermined where, as here, it would increase risks to women's health.

ARGUMENT

I. INTACT D&E HAS EVOLVED IN A MANNER CONSISTENT WITH OTHER SURGICAL TECHNIQUES AND ITS SAFETY AND HEALTH BENEFITS HAVE BEEN EQUALLY WELL DEMONSTRATED.

A. Contrary To Congress's Findings, Surgical Techniques Develop Without Reliance On Controlled Trials.

The development of new surgical techniques responds to surgery's unique demands and differs markedly from the way new therapies are developed in other areas of medicine. Initial development of surgical techniques and procedures rarely, if ever, depends on prospective research. Instead it evolves based on practitioner experience, observation and innovation. Surgical advancement commonly occurs when, in the course of performing an existing procedure, a physician

conceives of a way to improve the procedure through modification, tries the new method, and if successful, continues to employ it. See, *e.g.*, *Gonzales* v. *Carhart*, No. 05-380 (U.S.), Pet. App. 397a;[3] Sherwin B. Nuland, *Doctors: The Biography of Medicine* 410 (1988) (describing development of radical mastectomy; the procedure combined "the best features of all previous approaches" and took them one step further).

After a surgeon finds that his or her innovation appears to benefit patients, the surgeon informs others through a variety of means, ranging from formal conference presentations to more informal training sessions for institutional colleagues or communication with other physicians. Other surgeons then attempt the refined procedure, relaying to others word of their experiences with the technique and its safety and efficacy. Through these innovations and adaptations, the procedure evolves to the point that it is either discarded, or surgeons gain sufficient confidence to put it into regular practice and to determine whether it is the best and safest approach for a particular patient. See *e.g.*, Nuland, *supra*, at 410, 448-49 (discussing the spread of knowledge concerning various surgical procedures); *Carhart* Pet. App. 468a (citing William H. Frist & D. Craig Miller, *Repair of Ascending Aortic Aneurisms and Dissections*, 1 J. Cardiac Surg. 33, 45-46 (1986) (describing now-Senator Frist's view that surgeons rely on clinical experience to determine whether a surgical technique is appropriate)). Surgeons who, based on skill and experience, believe that a new surgical approach provides advantages for particular patients will not wait for the results of a large scale controlled study before putting the new approach into practice. *Carhart* Pet. App. 341a.

---

[3] Hereafter, *amici* refer to the Petitioner's Appendix in *Gonzales* v. *Carhart* as "*Carhart* Pet. App." and the appendices in *Gonzales* v. *PPFA* as "App." and "Pet. App."

Consistent with this approach to surgical innovation, the first published articles about a surgical innovation are likely to be retrospective and observational. *Id.* For example, a physician might publish outcomes of a particular procedure for one or more patients in a case study or series. In this situation, the physician has not treated patients in conformance with a predetermined study design. Instead, he or she has exercised his or her best clinical judgment at the time of treatment, carefully observed the outcomes, and reported the experience for the benefit of other experts in the field. The case study or series is a common way of sharing early individual experience, especially in the surgical community. Robin S. McLeod, *Issues in Surgical Randomized Controlled Trials*, 23 World J. Surg. 1210, 1213 (1999); Eric K. Fung, et al., *Randomized Controlled Trials for Evaluating Surgical Questions*, 128 Arch. Otolaryagol. Head Neck Surg. 631, 631 (2002); Pet. App. 143a. After treating a larger number of patients with a new surgical approach, a physician might publish a retrospective cohort study based on chart review. This type of study allows the researcher to compare and evaluate outcomes for two groups ("cohorts") of patients based on information contained in their medical charts. Pet. App. 109a.

Only much later—and only if an adequate sample size exists and medical ethics permit—can the modification be subjected to a prospective controlled trial.[4] See Claus Bartels et al., *Cardiopulmonary Bypass: Evidence or Experience Based?*, 124 J. Thorac. Cardiovasc. Surg. 20, 24-25 (2002). In prospective RCT research, patients are randomly assigned to either a group which will receive new treatment, or a

---

[4] It would be inappropriate to begin a controlled trial too soon after the introduction of a new surgical procedure. Among other reasons, the new procedure must be in existence long enough to be sufficiently familiar to surgeons so they may enroll an adequate number of participants, and the surgeons must be sufficiently experienced that operator variation can be controlled enough to satisfy scientific norms. McLeod, *supra*, at 1211.

control group which will receive an existing treatment. Fung et al., *supra*, at 631. In such trials, study designers attempt to control as many extrinsic factors as possible, removing confounding variables so that differences between the groups can be attributed to the new treatment and not patient- or physician-specific factors. McLeod, *supra*, at 1210; Fung, *supra*. RCTs, when possible, are often considered the most reliable form of medical research. McLeod, *supra*, at 1210; Fung, *supra*, at 631; but see Tom L. Beauchamp & James F. Childress, *Principles of Biomedical Ethics* 327 (5th ed. 2001) ("RCTs should not become indispensable rituals or necessary canons of valid research."); Kjell Benson et al., *A Comparison of Observational Studies and Randomized, Controlled Trials*, 342 New Eng. J. Med. 1878, 1883 (2000) (estimates of the effects of treatment in observational studies and randomized controlled trials were similar). Despite the acknowledged benefits of having RCT data, it is not always practical or even possible to conduct such trials, particularly for surgical advancement. Bartels, *supra*, at 24-25; Fung, *supra*, at 631-32; Michael J. Solomon & Robin S. McLeod, *Surgery and the Randomised Controlled Trial: Past, Present and Future*, 169 Med. J. Australia 380, 381-82 (1998).

The first barrier is surgeon enrollment. In some cases, by the time an adaptation has evolved to the point of being eligible for systematized study, it has already been embraced by surgeons, who cannot ethically participate in RCT study unless they believe there is uncertainty as to which approach is the most effective.[5] Albert R. Jonsen et al., *Clinical Ethics* 204 (6th ed. 2006); Bernard Lo, *Resolving Ethical Dilemmas: A Guide for Clinicians* 177 (3d ed. 2005). Otherwise, the

---

[5] This principle of genuine uncertainty is known as "equipoise." Clinical research ethics require that there be equipoise on the part of the individual clinical investigator or clinical equipoise about the preferred treatment within the expert medical community. Benjamin Freedman, *Equipoise and the Ethics of Clinical Research*, 317 New Eng. J. Med. 141, 141 (1987).

surgeon is ethically required to use what he or she believes is the safest and most effective technique for the particular patient. Lo, *supra*, at 177; Beauchamp & Childress, *supra*, at 327.

When there is sufficient doubt so that an RCT would be ethical, the nature of surgery nevertheless often renders the goal of randomization unattainable.[6] If, as is often the case, patients already have a preference for a particular procedure or technique, patient recruitment becomes an obstacle to randomized study. Fung, *supra*, at 632; Solomon & McLeod, *supra*, at 381.[7] Patient preference has frustrated efforts to conduct RCTs in a number of surgical contexts. See, *e.g.*, D. A. Grimes et al., *Mifepristone and misoprostal versus dilation and evacuation for mid-trimester abortion: a pilot randomized controlled trial*, 111 B. J. Obstet. Gynecol. 148, 148 (2004) (unable to conduct RCT because of vast patient

---

[6] In attempting to compare intact D&E to a dismemberment approach randomization is nearly impossible. As is discussed below, a physician does not know when beginning a D&E whether the fetus will present intact, or largely intact, or whether it will be necessary to dismember the fetus—even where the physician makes every effort to remove the fetus as intact as possible. Pet. App. 142a. Thus, a comparative study would be possible only by dividing procedures into two groups *after* the surgery—one more intact and one more dismembered—and comparing the complication types and rates as well as patient benefits. This type of retrospective cohort study is precisely the approach taken in the first study to attempt to compare dismemberment and intact variations or D&E. *See* Stephen T. Chasen et al., *Dilation and Evacuation at ≥ 20 Weeks: Comparison of Operative Techniques*, 190 Am. J. Obstet. & Gynec. 1180 (2004) (App. 1055-70) (hereinafter "Chasen, *D&E*").

[7] Randomization is also unappealing to surgeons who believe that it requires the surgeon to acknowledge ambivalence as to which treatment approach is safest and thus compromises apparent authority and expertise. R. Lefering & E. Neugebauer, *Problems of Randomized Controlled Trials (RCT) in Surgery* (1997), *available at* http://www.symposion.com/nrccs/lefering.htm; *see also* Fung, *supra*, at 632. In turn, the hesitancy of surgeons to participate and solicit their patients for studies exacerbates the problem of patient recruitment. Lefering & Neugebauer, *supra*.

preference for D&E over induction abortion); McLeod, *supra*, at 1212 (unable to conduct trial comparing mastectomy to lumpectomy).

Even when surgical studies can be randomized, they are hard to standardize and control. For example, variations in skill and training among surgeons make standardization difficult to achieve. If different surgeons operate on different patients, it may be impossible to determine whether the success of a procedure is attributable to the procedure or to the surgeon's skill in executing it. David S. Jones, *Visions of Cure: Visualization, Clinical Trials, and Controversies in Cardiac Therapies, 1968-1998*, 91 Isis 504, 523 (2002); Fung, *supra*, at 632-33; McLeod, *supra*, at 1210. Having a single surgeon conduct every surgery in a study could theoretically solve the standardization problem. Lefering & Neugebauer, *supra*. However, no surgeon can conduct a procedure in the exact same way every time. A surgeon must respond to patient- and procedure-specific circumstances that arise during the surgery, making it impossible to standardize multiple procedures. McLeod, *supra*, at 1210; see Joel E. Frader & Donna A. Caniano, *Research and Innovation in Surgery, in Surgical Ethics* 216, 216 (Laurence B. McCullough et al. eds., 1998) ("Even on the same day, with similar patients, a single surgeon may perform 'the same' procedure somewhat differently, due to anatomic or physiologic differences among patients or for other reasons.").[8]

These barriers are especially problematic when the surgical techniques being compared have low complication and high success rates, as is the case with all variations of D&E. Pet. App. 141a. In such cases, a study can only produce

---

[8] Furthermore, the more a surgeon performs a technique or procedure, the more effective he or she becomes, thereby reducing the complication rates on the procedure over time—again undercutting standardization. Fung, *supra*, at 632-33.

statistically significant results if it includes a high volume of participants. The barriers to participation discussed above can thus render RCTs impossible.

As a result, surgeons frequently rely on other methods of attaining confidence in a new or modified surgical procedure. Congress's artificial notion that RCTs are necessary to demonstrate the safety and efficacy of a particular surgical procedure is inaccurate and flatly inconsistent with the standards to which surgical professionals currently adhere. As illustrated below, the development of intact D&E is consistent with the standards applied to other surgical innovations. If Congress had banned surgical procedures at this stage of development on an RCT rationale, the nation would have been deprived of the benefits of some of the most important surgical advancements in the past century.

One of the greatest surgical developments of the twentieth century is the widespread use of minimally invasive laparoscopic techniques. Because the laparoscopic incision is much smaller than the incision in a traditional "open" procedure, patients have less pain, shorter hospital stays, briefer recovery periods and reduced scarring. See, *e.g.*, U. Giger et al., *Laparoscopic Cholecystectomy in Acute Cholecystitis: Indication, Technique, Risk and Outcome*, 390 Langenbecks Arch. Surg. 373, 373 (2005). As a result, even in the absence of controlled trials demonstrating relative effectiveness and safety, laparoscopic surgery became the method of choice for surgeons and patients almost as soon as its use became an option.

Laparoscopic surgery requires only small incisions through which the surgeon passes surgical instruments and removes tissue. Instead of direct visualization, the surgeon observes the target of the surgery through a small camera with the image projected onto a screen in the operating room. Laparoscopic surgery evolved from the use of an endoscope to visualize the interior of the human body for diagnostic purposes. G.S. Litynski & V. Paolucci, *Origin of Laparo-*

scopy: Coincidence of Surgical Interdisciplinary Thought?, 22 World J. Surg. 899, 900-01 (1998). Early endoscopes—first just small mirrors with illumination—were inserted into the abdomen to permit visualization of internal organs without large incisions. See *id.* Surgeons later adapted the technology for surgical use by inserting specialized surgical instruments through other small incisions and visualizing the operating area through the endoscope.

One application of this surgical innovation is the laparoscopic cholecystectomy, used to remove a diseased gall bladder for treatment of gallstones. The traditional method of cholecystectomy, the "open" method (in which the surgeon makes an incision large enough to visualize and touch the gall bladder and the interior of the abdomen), was first performed in 1882, and for more than 100 years was the "gold standard" for treatment of gall bladder disease. See Giger, *supra*, at 373; Thomas R. Gadacz et al., *Traditional Versus Laparoscopic Cholecystectomy*, 161 Am. J. Surg. 336, 337 (1991). In the mid-1980s, a German surgeon performed the first reported laparoscopic cholecystectomy. Giger, *supra*, at 373; see also J. Barry McKernan, *Origin of Laparoscopic Cholecystectomy in the USA: Personal Experience*, 23 World J. Surg. 332, 333 (1999). Word of this innovation spread through conversations and at conferences. See Thomas L. Dent et al., *Minimal Access General Surgery: the Dawn of a New Era*, 161 Am. J. Surg. 323, 323 (1991) (videotape of procedure shown at conference in 1989).

After anecdotal results were presented to surgeons, patients became aware of its benefits through reports in the lay press. Lefering & Neugebauer, *supra*. Patients began insisting that their cholecystectomies be performed laparoscopically. Within six years of the first laparoscopic cholecystectomy, and despite the absence of formal clinical trials establishing safety and effectiveness, the method became widely available in both the United States and Europe. C. Randle Voyles, *A*

Practical Approach to Laparoscopic Cholecystectomy, 161 Am. J. Surg. 365, 365 (1991).

In fact, researchers had difficulty recruiting patients for controlled trials testing laparoscopic cholecystectomy against the open method because "initial reports and articles in the lay press" suggested that the laparoscopic method was far superior to the open method. Lefering & Neugebauer. *supra.* In 1992, the National Institutes of Health concluded that "laparoscopic cholecystectomy provides a safe and effective treatment" for removal of gall bladder for treatment of gall stones, while acknowledging that "well-controlled studies [of its comparative benefits] are unavailable, and there is little prospect that such studies will be done." *Gallstones and Laparoscopic Cholecystectomy*, NIH Consensus Statement 10(3) (Sept. 16, 1992), *available at* http://consensus.nih.gov/1992/1992GallstonesLaparoscopy090html.htm.

Laparoscopic surgery is but one example of this recurring evolutionary phenomenon. Other procedures, including radical mastectomy, the B-Lynch suture, coronary artery bypass grafting ("CABG"), angioplasty, and coronary pulmonary bypass similarly evolved through surgical practice. See, *e.g.*, Jones, *supra*, at 513-16 (discussing evolution of CABG, which came into practice in 1967, and noting that despite lack of RCTs, 100,000 CABGs had been completed by 1974); see also *id.* at 538-39 (angioplasty was first performed in 1977, and the first comparative trials were not published until 1992).

B. The Evolution Of Intact D&E Comports With The Standards For Safety And Efficacy In Surgical Advancement.

The intact approach to D&E came into existence in the same manner as these other surgical procedures: surgeons modified an existing technique to reduce risks, discussed their successful surgeries with colleagues, and slowly began to present the new variation formally at meetings and in journal

publications. As a result, intact D&E has become accepted as safe for terminating second trimester pregnancy, and is widely endorsed by physicians, including those practicing at some of the most prestigious teaching institutions in the country. Pet. App. 205a. These physicians believe, based on extensive experience, that removing the fetus as intact as possible is the safest approach for all patients, and that doing so is particularly important for certain patients in already compromised medical conditions. *Carhart* Pet. App. 497-500a; Pet. App. 143-44a, 147a.

The most appropriate abortion procedure for a particular patient is based on a number of factors, including gestational age. In a vacuum or suction curettage—the most common method in the first trimester—the cervix is dilated and a manual or electric suction tool is used to evacuate the uterus. Phillip G. Stubblefield et al., *Methods for Induced Abortion*, 104 Obstet. & Gynec. 174, 175-76 (2004). Because of the relatively small size of an embryo or first-trimester fetus, this tool alone typically can remove the fetus and all products of conception. But as pregnancy progresses, the small tools and limited dilation achieved during vacuum aspiration become inadequate to empty the uterus safely.

As a result, in the early 1970s, abortion after 12-weeks gestation generally took place in a hospital by labor induction. *Id.* at 179. However, with the advent of safe methods for greater cervical dilation at this later stage of pregnancy, it became possible to perform surgical terminations (D&E) throughout the second trimester. W. Martin Haskell et al., *Surgical Abortion After the First Trimester, in A Clinician's Guide to Medical & Surgical Abortion* 123 (Maureen Paul et al. eds., 1999) (hereinafter "*Clinician's Guide*"); see also Pet. App. 65-66a; *Carhart* Pet. App. 399a. Compared to labor induction, D&E offered abortion patients a significantly shorter procedure, with less pain and discomfort, that could be provided on an out-patient basis. Pet. App. 142a. While D&E required greater skill on the part of the physician,

because of its advantages, D&E quickly became recognized as the safest method of terminating pregnancy in the second trimester. *Clinician's Guide*, *supra*, at 125; see also Chasen, *D&E* at 1180 (App. 1057).

In D&E, after the cervix is dilated, the physician uses grasping tools such as a forceps to remove the fetus and the placenta from the uterus. Stubblefield et al., *supra*, at 179. In many cases, the fetus disarticulates as it is grasped and drawn through the cervix. Pet. App. 60a. Though extremely safe, D&E with disarticulation (or dismemberment) carries potential risks, which although rare, can be devastating.[9] Specifically, the approach involves repeated passes of instruments through the cervix into the uterus and removal of bony fragments, both of which create a risk of perforation or laceration of the highly vascularized uterus and/or cervix, some of the most feared complications of D&E. Chasen, *D&E* at 1183 (App. 1063-64); Pet. App. 144a; see also *Nat'l Abortion Fed'n* v. *Ashcroft*, 330 F. Supp. 2d 436, 471 (S.D.N.Y. 2004), *aff'd in part sub nom.* 437 F.3d 278 (2d Cir. 2006).

As dilation techniques evolved, physicians began to seek wider cervical dilation to facilitate evacuation, which increases the chances of removing the fetus as intact as possible. Stubblefield, *supra*, at 179; Chasen, *D&E* at 1183 (App. 1063); *Clinician's Guide*, *supra*, at 136. Intact removal obviates the need for repeated passes with instruments and removal of sharp bony fragments. *Carhart* Pet. App. 497-98a; Pet. App. 144a. It gives the surgeon certainty that all

---

[9] In medicine, the term "risk" encompasses both probability and gravity. The first study comparing intact D&E to D&E with dismemberment, showed general complication rates were the same, but all serious complications were in the dismemberment group, Chasen, *D&E* at 1183 (App. 1063). This evidence of intact D&E's safety was particularly significant since the intact procedures occurred later in gestation, so researchers had expected to see more complications from that group. Pet. App. 117a; *Carhart* Pet. App. 359a.

fetal tissue has been removed, reducing the risk of infection, and offers the potential for shorter operating times, and thus less time under anesthesia. *Carhart* Pet. App. 497-98a; Pet. App. 144a.[10]

While physicians have long known of the benefits of minimizing instrumentation, the first presentation that suggested techniques to maximize the chance of intact removal took place in 1992. It was delivered by Dr. Martin Haskell at a conference of the National Abortion Federation ("NAF"). Dr. Haskell described both dilation techniques and intra-operative techniques used to maximize the possibility of intact removal. See Martin Haskell, *Dilation and Extraction for Late Second Trimester Abortion* 127-28, Presented at Nat'l Abortion Fed'n, Second Trimester Abortion: From Every Angle Seminar (Sept. 13, 1992). Three years later, another physician presented a retrospective observational paper regarding his experience performing an intact variation of D&E. See James T. McMahon, *Intact D&E: The First Decade* at 19, Presentation at NAF Conference (Apr. 2, 1995); see also *Clinician's Guide*, *supra*, at 136.

Following these presentations, other physicians took steps to incorporate aspects of what these physicians called

---

[10] Intact D&E also offers psychological benefits and the possibility of increasing a woman's success in carrying future pregnancies to term. Many abortions that take place later in the second trimester are of pregnancies that are very much wanted, but which the patient elects to terminate after learning that she is suffering from a medical condition inconsistent with carrying the pregnancy to term, or that her fetus suffers from an anomaly making sustained survival outside the uterus unlikely. App. 105-08, 208-11, 257-60, 391, 420. These patients often wish to see and hold the fetus, and mourn its death. Pet. App. 105a, 142-43a; *Clinician's Guide*, *supra*, at 136. Moreover, an intact specimen allows for a more complete and sophisticated evaluation of the anomalies with which the fetus was afflicted. Pet. App. 105a; App. 924-25. For patients hoping to later carry a healthy pregnancy to term, information obtained from such an evaluation can be critical to reducing the risk of future pregnancy problems. App. 130-31, 501-02, 924-25.

"dilation and extraction" or "intact D&E" into their own practices. While some physicians adopted an approach similar to that presented, others adapted variations more consistent with their own techniques and circumstances and those techniques continued to evolve through informal communication among practitioners. Pet. App. 67-68a. As this evolution continued, intact removal began to be taught at medical schools, Pet. App. 205a.; *Carhart* Pet. App. 473a, discussed in medical literature, see, *e.g.*, *Clinician's Guide*, *supra*, at 136-37; Stubblefield, *supra*, at 179 and endorsed by leading medical organizations. See, *e.g.*, ACOG Statement of Policy (Jan. 1997, *reaff'd*, Sept. 2000, *reaff'd*, July 2004).

In 2004, Dr. Stephen Chasen, Director of High Risk Obstetrics at New York Presbyterian-New York Weill Cornell Medical Center, and his colleagues published the results of a retrospective case review of patients who underwent surgical abortion at 20 weeks or later in pregnancy at Weill-Cornell Medical Center from 1996-2003. See Chasen, *D&E* at 1180 (App. 1055-70). This study compared outcomes for two cohorts: 1) those whose terminations were achieved largely intact, as defined in the study, and 2) those whose terminations were through dismemberment. *Id.* (App. 1059). It concluded that an intact variation of D&E was as safe as D&E with dismemberment, see *id.* at 1180 (App. 1059), and possibly safer. Pet. App. 117a; *Carhart* Pet. App. 359a; see also Chasen, *D&E* at 1182-83 (App. 1062-63). Dr. Chasen and his colleagues subsequently published a retrospective analysis of the risks of subsequent pre-term birth for the patients in these two cohorts. See Stephen T. Chasen et al., *Obstetric Outcomes After Surgical Abortion at ≥ 20 Weeks' Gestation*, 193 Am. J. Obstet. Gynec. 1161 (2005). Dr. Chasen has presented his study results at conferences, thus furthering the academic discussions about the safety and successes of the variations of D&E. See, *e.g.*, Stephen T. Chasen, *Surgical Abortion in the Second Trimester*,

Presentation at NAF Risk Management Conference (Oct. 2004).

This level of study—presentations at conferences, discussions among colleagues and publication of the retrospective case reviews—is consistent with the way surgical advancement has been evaluated historically. As Government expert, Dr. Watson Bowes, testified, the Chasen study is an appropriate and important first step in studying this variation of D&E. App. 577. Moreover, as with other surgical procedures, the absence of prospective controlled trials has proved immaterial to the conclusions drawn by learned surgeons that intact D&E carries with it significant health advantages. Any desire to conduct prospective, controlled trials of intact D&E would be frustrated by all of the challenges of surgical research in general, see *supra* at 6-10, as well as procedure-specific obstacles that make such study a near impossibility. See generally App. 384-89 (discussing the infeasibility of prospective controlled studies of second trimester abortion methods). As noted, even when trying to remove the fetus as intact as possible, physicians cannot know at the beginning of a D&E procedure whether the fetus will present intact or largely intact, or whether it will be necessary to dismember. Pet. App. 142a. As a result, patients cannot be prospectively randomized, and only a retrospective comparative study, like Dr. Chasen's, is even possible. See Chasen, *D&E* at 1180 (App. 1055-70).

In addition, because complication rates for D&E overall are very low, a study comparing relative complication rates for dismemberment and intact variations would need to include a great number of patients in order to find a statistically significant difference. App. 385-87 (recognizing that thousands of women would have to participate to reach statistical significance). Given that the universe of patients seeking pregnancy termination at the stage of gestation when intact removal may be successful on a relatively regular basis is very small, see *Abortion Surveillance—United States 2002*,

54 *Morbidity & Mortality Weekly Report* (Center for Disease Control & Prevention), Nov. 25, 2005, at 21 tbl.6, reaching a statistically significant result would be nearly impossible.

Furthermore, as discussed above, recruitment into prospective controlled surgical studies presents a particular challenge, as both patients and surgeons are hesitant to limit their surgical choices based on the parameters of a study. Many physicians believe that it is always safer to remove the fetus as intact as possible. Accordingly, it would be enormously difficult to recruit them into a study in which they agreed to attempt to dismember the fetus—something they believe to be less safe for their patients. See *supra* note 5 (discussing principle of individual and clinical equipoise).

The Act would prevent research of the relative safety of second trimester abortion options and would restrict physicians from attempting additional modifications aimed at further reducing complication rates and increasing safety. While infrequent, the serious complications that intact D&E can help to prevent can be catastrophic when they occur. Prohibiting intact D&E would deprive women of the best medical judgment in the field and of the significant health benefits the medical profession has recognized are associated with reducing these risks.

II. THE HEALTH BENEFITS OF INTACT D&E MANDATE THAT IT BE CONSTITUTIONALLY PROTECTED.

As demonstrated above, Congress has attempted to justify a ban on safe abortion procedures by imposing an artificial and unrealistic standard for judging safety that the surgical community does not impose on itself, and that as a practical matter can never be the sole standard by which surgeons judge the safety and health benefits of new procedures. This Court has long recognized that the constitutionality of regulations affecting abortion must be considered in light of the medical profession's standards of judgment. *City of*

Akron v. *Akron Ctr. for Reprod. Health, Inc.*, 462 U.S. 416, 434 (1983) (stating that a regulation of abortion that "departs from accepted medical practice" may not be upheld), *overruled on other grounds by Planned Parenthood* v. *Casey*, 505 U.S. 833 (1992);[11] *Planned Parenthood* v. *Danforth*, 428 U.S. 52, 79 (1976) (striking down abortion ban that would have "force[d] a woman and her physician to terminate her pregnancy by methods more dangerous than the method outlawed"); see also *Simopoulos* v. *Virginia*, 462 U.S. 506, 519 (1983) (upholding requirement that second-trimester abortions be performed in licensed clinics because the requirement "comport[s] with accepted medical practice, and leaves the method and timing of the abortion precisely where

---

[11] Justice Kennedy's suggestion that *Casey* "repudiated" this aspect of *Akron* is misplaced. *Stenberg* v. *Carhart*, 530 U.S. 914, 969 (2000) (Kennedy, J., dissenting). While Justice Kennedy is correct that in overruling *Akron*'s informed consent holding, *Casey* repudiated those portions of *Akron* which suggested that deference to the individual physician was mandated, *compare Planned Parenthood* v. *Casey*, 505 U.S. 833, 884 (1992) (plurality opinion), *with Akron*, 462 U.S. at 445, *Casey* did nothing to curtail the deference the *Akron* Court had paid to professional standards in striking down the hospitalization requirement, *compare Casey*, 505 U.S. at 881-86 (plurality opinion), *with Akron*, 462 U.S. 430 n.11; *id.*, at 435-36; *id.* at 437 (noting: "ACOG [American College of Obstetricians and Gynecologists] no longer suggests that all second–trimester abortions be performed in a hospital. It recommends that abortions performed in a physician's office or outpatient clinic be limited to 14 weeks of pregnancy, but it indicates that abortions may be performed safely in 'a hospital-based or in a free-standing ambulatory surgical facility,' until 18 weeks of pregnancy. These developments, and the professional commentary supporting them, constitute impressive evidence that-at least during the early weeks of the second trimester-D & E abortions may be performed as safely in an outpatient clinic as in a full-service hospital.") (internal citations omitted); *see also id.* at 437 n.26 (discussing the government's own reliance on ACOG standards.). Indeed, as this Court has recognized, what is accepted medical practice according to ACOG is highly relevant to determining if there is "substantial medical authority" in support of a procedure. *E.g.*, *Stenberg*, 530 U.S. at 938; *Akron*, 462 U.S. 416.

they belong—with the physician and the patient"). Viewed through the same lens that surgical professionals would, it becomes clear that intact D&E has been shown to be safe and to provide tangible and substantial health benefits. *Supra* Part I.B.

This law unquestionably jeopardizes women's health, with a veiled pretense of concern for safety. To uphold the Act, then, would mark a sea change in this Court's jurisprudence because never before has this Court held that a government interest in a particular abortion regulation outweighed the combined strength of the state's and the woman's interest in her health.

A. Women's Health Is Primary To, If Not Dispositive Of, The Constitutional Analysis.

Joining an unbroken line of this Court's precedents, *Stenberg* v. *Carhart* held that "a State may promote but not endanger a woman's health when it regulates the methods of abortion." 530 U.S. 914, 931 (2000) (collecting cases); *accord Ayotte* v. *Planned Parenthood*, 126 S. Ct. 961, 967 (2006); see *Casey*, 505 U.S. at 879 (plurality opinion). Where this Court has recognized that an interest in protecting women's health is implicated by a potential restriction on abortion, that interest has *always* overcome the competing interests advanced by the state. See, *e.g.*, *Ayotte*, 126 S. Ct. at 967; *Stenberg*, 530 U.S. at 929-31; *Thornburg* v. *Am. Coll. of Obstetricians & Gynecologists*, 476 U.S. 747, 769 (1986), *overruled on other grounds by Casey*, 505 U.S. 833; *Danforth*, 428 U.S. at 79; see *Colautti* v. *Franklin*, 439 U.S. 379, 400 (1979) (women's health is "paramount"). This is hardly surprising, for not only is women's health a fundamental right in abortion jurisprudence, but women's health and safety are themselves compelling state interests. See, *e.g.*, *Casey*, 505 U.S. at 977 (Rehnquist, C.J., dissenting) (state interest in women's health); *Danforth*, 428 U.S. at 80-81 (upholding recordkeeping requirements directed at preservation of women's health); *Akron*, 462 U.S. at 428-29,

430-31, 443; *id.* at 459 (O'Connor, J., dissenting) (state has interests in "the areas of health and medical standards," as well as "maximum" safety for women).

A woman's fundamental right to her health is so great that even post-viability, when the state's interest in potential life is so strong as to permit the state to ban abortion altogether, this Court has pointedly refused to allow that interest to override the woman's (and the state's) interests in her health. When necessary for the health of the woman, an abortion must be allowed, even after viability. *Casey*, 505 U.S. at 879 (plurality opinion) ("'subsequent to viability, the State in promoting its interest in the potentiality of human life may, if it chooses, regulate, and even proscribe, abortion except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother'") (quoting *Roe* v. *Wade*, 410 U.S. 113 164-65 (1973)). These longstanding principles require that the decision below be affirmed because the Act will put women's health at risk.

The *Stenberg* Court correctly recognized that an intact approach to D&E offers safety advantages for women. See generally 530 U.S. at 931-37 (discussing general and specific advantages of intact variation.). In doing so, the *Stenberg* Court took the modest step of affirming what physicians had discovered to be true over the years in which they had explored different variations of D&E, seeking to provide the safest and most effective procedures for their patients. *Supra* at 12-17. Indeed, this Court properly recognized that considerable physician experience with intact D&E—which has grown dramatically since *Stenberg*—provided strong evidence of the benefits of the surgical innovation. This conclusion is bolstered by the fact that dismemberment D&E constituted an evolutionary alternative to labor induction nearly two decades earlier. See *supra* at 13-14.

B. Banning An Intact Approach To D&E Denies Women A Potential Health Benefit By Increasing The Health Risks They Face.

Some of *Stenberg*'s critics do not deny that women's interest in their health is so great that it cannot be overcome by the state's competing interests. Instead, they have charged that this and similar statutory schemes pass constitutional muster because there has been no showing that such bans "create[] a significant health risk." *Nat'l Abortion Fed'n* v. *Gonzales*, 437 F.3d 278, 291 (2d Cir. 2006) (Walker, C.J., concurring); see also, *e.g.*, *Stenberg*, 530 U.S. at 966-72 (Kennedy, J., dissenting); *Planned Parenthood* v. *Doyle*, 162 F.3d 463, 478 (7th Cir. 1998) (Manion, J., dissenting).

For example, Chief Judge Walker asserted that "in all circumstances there are objectively 'safe' alternatives" to intact D&E. *Nat'l Abortion Fed'n*, 437 F.3d at 291. Based on his posited notion of objective "safety," Chief Judge Walker characterized the ban as a mere "den[ial to] some women [of] a potential health *benefit* over an objectively 'safe' baseline; it does not establish that such a statute would pose a constitutionally significant health *risk*." *Id.* In essence, his argument is that alternatives exist that are "safe enough."

Chief Judge Walker's artificial distinction between the denial of a health benefit and an increased health risk does not withstand scrutiny. There is no such thing as a completely "safe" surgery, because by definition surgery disrupts the physical integrity of the body, and all such disruptions involve some harm. Although years of surgical experience brought about consensus that D&E is a relatively safe procedure which should continue to be practiced to maximize the health of women who need abortions, D&Es of all variations, like all surgical procedures, carry risks. When intact procedures reduce those real and potentially catastrophic risks, it makes no sense to talk about a dismemberment approach to D&E as inherently or objectively

safe. Moreover, any such discussion of an objective level of safety accompanying one approach to abortion or another is inherently flawed because, in every event, any approach to abortion is considerably safer in the abstract than child birth. David A. Grimes, *Estimation of Pregnancy-Related Mortality Risk by Pregnancy Outcome, United States, 1991-1999*, 194 Am. J. Obstet. & Gynec. 92, 92-93 (2006) (concluding "[t]he relative [mortality] risk associated with live birth was 12.4 times higher" than that associated with legal abortion).

There is no distinction between risk and benefit in the D&E context. Rather, they are two inseparable sides of the same coin. See Beauchamp & Childress, *supra*, at 194-95 (stating "[b]enefit" compares to harm, as "risk"—which can refer to chance of harm, or the potential magnitude of harm—compares to "probability of benefit"). Like all patients, a woman terminating a pregnancy in the second trimester seeks to minimize the risk of harm associated with the procedure. If the physician concludes that D&E with intact removal will reduce the risks for a particular patient, Chief Judge Walker would apparently recognize that such a patient is receiving a health benefit. In his view, however, withholding this benefit is permissible because the less safe procedure still satisfies some arbitrary but minimalist notion of "safe." Yet the health benefit denied here is an increase in safety—in other words, the reduction of risk. Accordingly, when this "benefit" is denied, the woman is not merely deprived of an advantage, but is inherently put at risk.

Surgeons simply do not think of safety in the kind of absolute terms Chief Judge Walker has posited. It is senseless for a court to attempt to evaluate the magnitude of a health benefit against some objective notion of what is "safe." Cf. *United States* v. *Rutherford*, 442 U.S. 544, 555 (1979) ("Few if any drugs are completely safe in the sense that they may be taken by all persons in all circumstances without risk."). To the contrary, even medical procedures that are performed safely in the overwhelming majority of cases

present health risks, and in particular cases the minimal risk manifests as substantial injury. See, *e.g.*, *Fulton* v. *Loucks*, 947 F.2d 944 (6th Cir. 1991) (table) (appeal of wrongful death action by parents whose son died days after having his tonsils removed).

In surgery and in medical practice generally, physicians always strive for the safest treatment *under the circumstances*. In any given surgery, factors such as the individual patient's health history and his or her use of medications, as well as the physician's judgment as to which risks are acceptable to the overall health of the patient make the concept of "safety" in the context of surgery transient at best. In addition, risks are always understood in relation to benefits. A certain level of risk might be acceptable for a procedure that excises a deadly cancer and unacceptable for elective surgery. Finally, the circumstances as they present when the surgeon initially assesses treatment options may evolve during the procedure, altering what actions are and are not safe. These variables dispel any claims that an "objectively 'safe' baseline" exists. Cf. *Anderson* v. *Weinsweig*, 34 Fed. Appx. 916, 917 (4th Cir. 2002) (per curiam).[12]

The enhanced safety of intact D&E is well-recognized by physicians. Of course, patient- or fetus-specific circumstances known at the outset (for example, gestational age) may make an actual intact extraction unlikely. Likewise, circumstances that arise during the procedure may frustrate

---

[12] In *Anderson*, the Fourth Circuit detailed the multiple variables faced by a physician where a patient's foot bothered him before undergoing planned brain surgery. As the Fourth Circuit noted, the doctor determined "the problems arose from constricted blood flow; that this constriction could not be treated without administering blood thinners; that these blood thinners, combined with inevitable delays in performing the brain surgery, might exacerbate the problems in [the patient's] brain; and that it was therefore appropriate to proceed with the brain surgery even though doing so might have adverse consequences for [the patient's] foot," and indeed the delay led to amputation of two toes. 34 Fed. Appx. at 917.

the attempt to accomplish the removal intact. In addition, physician training or protocols, or patient medical circumstances may result in less dilation and less chance of intact removal. What matters is that physicians be permitted to exercise their professional judgment based on their experience and training and the state of the medical art to perform a D&E procedure in the manner that maximizes patient safety and health. See *Stenberg*, 530 U.S. at 923-29.

A responsible physician who is performing a second trimester abortion would not merely ask whether an alternative approach satisfies some contrived notion of "safe enough." Physicians' ethical commitments to their patients require that they maximize patient safety within the parameters of learned professional judgment. See Beauchamp & Childress, *supra*, at 115 (the principle of beneficience requires one to prevent harm, remove harm and do good; the principle of nonmaleficence requires one to not inflict harm); ACOG, *Ethics in Obstetrics and Gynecology* at 4 (2d ed. 2004) (same); *Planned Parenthood Ass'n* v. *Ashcroft*, 462 U.S. 476, 487 (1983); *Akron*, 462 U.S. at 434 (acknowledging value of accepted medical standards); *Dent* v. *W. Virginia*, 129 U.S. 114, 122-23 (1889). A law criminalizing the safest methods of abortion for particular patients—especially where the banned methods accord with substantial medical authority—would put physicians in a terrible ethical dilemma: betray their duty to their patient, or betray the obligation to follow the law. Just as deference has been paid to physicians' collective expertise as they have developed innovative medical procedures through years of observation and refinement, deference is owed when surgeons determine how to put their knowledge, training and experience to use to advance health and safety in a given case. Because physicians must seek to optimize safety for every patient they treat, a prohibition against safe abortion methods undermines their collected experience and the resulting procedures carry enhanced risks. A government restriction that deprives

physicians of the full range of options within their professional medical judgment and expertise—and in accord with authoritative medical standards—thus offends the constitutional requirement that women not be forced to undergo methods of abortion that are riskier than those that would be available absent the restriction. See *Stenberg*, 530 U.S. at 931.

III. ADOPTING THE GOVERNMENT'S POSITION WOULD MARK A SEA CHANGE IN THIS COURT'S ABORTION JURISPRUDENCE.

This Court's precedents share an unwavering commitment to protecting maternal health as the predominant consideration in determining the constitutionality of a restriction on abortion. The constitutional analysis the Government advocates—which repudiates this framework—cannot be squared with this Court's precedents.

A. This Court Should Reject The Claim That Preventing Abortion Which "Resembles Infanticide" Is A Compelling Interest Sufficiently Strong To Overcome Women's Interest In Access To The Safest Abortion Procedure.

The Government urges this Court to recognize a novel compelling state interest, *viz.*, "prohibiting a particular type of abortion procedure that closely resembles infanticide." U.S. Br. 28. The Government goes so far as to argue that this "interest" in preventing procedures resembling infanticide is "*no less compelling*" than its interest in protecting human life, *id.* (emphasis added); in turn, the Government's argument suggests that this novel interest also outweighs the woman's interest in safety. See *id.* at 10, 24, 27; see also *id.* at 28.[13]

---

[13] Comparing the abortion procedures at issue in this case—all of which occur prior to viability—to infanticide is curious from the outset. *See, e.g.*, *Oxford English Dictionary* (2d ed. 1989) (defining infanticide and its origins in a manner presuming viability); *American Heritage Dictionary of the English Language* (4th ed. 2000) (defining "infanticide" as "*1.* The

The Government's effort to elevate its purported interest in preventing abortion that supposedly resembles infanticide to one so compelling as to outweigh the paramount interest in women's health should be rejected.

First, in advancing the infanticide interest as controlling, the Government turns the prevailing constitutional analysis on its head. Without doctrinal foundation, the Government attempts to subvert the heretofore predominant interests in women's health, the potential for human life and medical progress. Adopting the Government's proposed compelling interest where, as here, the woman has already determined that the pregnancy should be terminated and where the procedure is occurring prior to viability, would deal a massive blow to the woman's health interests. Focusing on *how* the pregnancy will be terminated, rather than the nature of the health deprivation, would rework this Court's cases that "have repeatedly invalidated statutes that in the process of regulating the *methods* of abortion, imposed significant health risks." *Stenberg*, 530 U.S. at 931 ("a risk to a women's [sic] health is the same whether it happens to arise from regulating a particular method of abortion, or from barring abortion entirely"). If the Court were to adopt the moral condemnation approach that the Government urges, the result would be breathtaking, allowing the interest in women's health to be trumped even pre-viability where the state interests have long been recognized as "considerably weaker than postviability." *Stenberg*, 530 U.S. at 930 (citing *Casey*, 505 U.S. at 870).

Second, this Court recently rejected a criminalization argument by the federal government directly parallel to the one it now advances. See *Ashcroft* v. *Free Speech Coalition*, 535 U.S. 234 (2002). In enacting the Child Pornography

---

act of killing an infant. *2.* The practice of killing newborn infants."). *See also Stenberg*, 530 U.S. at 946-47 (Stevens, J., concurring) (notion that one form of D&E "is more akin to infanticide than the other, or that the State furthers any legitimate interest by banning one but not the other, is simply irrational").

Prevention Act, Congress sought to go beyond the preexisting ban on child pornography by criminalizing images that looked like child pornography but did not involve actual children. Reasoning that the indirect government interest in prohibiting the *appearance of* child pornography was not sufficient to outweigh the First Amendment protection at issue, the Court held that only direct harm to real children could justify such an imposition on the fundamental right. See *id.* at 248-51. Moreover, the Court squarely rejected the Government's argument that prohibiting otherwise protected conduct as a means to prevent already impermissible actions was a compelling interest that allowed infringement of the speech right. See *id.* at 254-55. Applied here, the same fundamental rights analysis prevents the government from prohibiting intact D&E, which would otherwise be lawful, as an attempt to prevent infanticide, which is already subject to criminal penalty.

Finally, this Court's precedent forecloses the Government's effort to impose morality as a compelling interest that would override a fundamental right. In *Lawrence* v. *Texas*, 539 U.S. 558 (2003), this Court firmly rejected the proposition that moral concerns alone could ground a statute that infringes upon the right to autonomy protected by the due process clause. *Id.* at 571 ("These [moral] considerations do not answer the question before us, however."). The fact of moral objection standing alone was insufficient to prove that the morality rationale would constitutionally justify "us[ing] the power of the State to enforce these views on the whole society through operation of the criminal law." *Id.*; see also *Romer* v. *Evans*, 517 U.S. 620, 634-35 (1996) (legislation cannot be justified by animosity toward a class of persons); *Lawrence*, 539 U.S. at 583 (O'Conner, J, concurring) ("moral disapproval" is not a legitimate state interest sufficient to ban one form of sodomy but not another). Just as in the equal protection context where it would not even rise to the level of a rational basis to express animus to a particular group, see,

e.g., *United States Dep't of Agric.* v. *Moreno*, 413 U.S. 528, 534 (1973) (holding "a bare . . . desire to harm a politically unpopular group cannot constitute a legitimate government interest") (emphasis omitted); *Romer*, 517 U.S. at 635 (finding "the breadth of the amendment [was] so far removed from [its asserted] justifications" that it was not "directed to an identifiable legitimate purpose or discrete objective" but "raise[d] the inevitable inference that it [wa]s born of animosity"), in this case the displeasure with a certain type of incidental procedure could never rise to the level of a compelling government interest sufficient to overcome a fundamental right. See *Saenz* v. *Roe*, 526 U.S. 489, 499 n.11, 506 (1999) ("If a law has no other purpose . . . than to chill the assertion of constitutional rights by penalizing those who choose to exercise them, then it [is] patently unconstitutional"; thus, a purpose to deter welfare applicants from migrating to California was an "unequivocally impermissible" government interest) (alteration and omission in original) (quotation omitted). The Act's overbreadth and incomplete-reasoning—no more than direct attacks on otherwise-protected conduct—give rise to a strong inference of simple animus, assertions of moral rectitude notwithstanding, which this Court has never dignified as a constitutional basis for an infringement on a fundamental right.

B. This Court Rightly Has Never Held That A Restriction On Abortion May Survive Even Though It Would Increase Risks To Women.

Although the Government claims that prohibiting intact D&E would not impinge on women's health interests, it also asserts that even if intact D&E reduces health risks, the increased risks to the woman associated with banning such procedures are nonetheless insufficient to require constitutional protection. See U.S. Br. 28. In doing so, the Government urges this Court to hold for the first time that the "relative strength of the government's interests prohibiting partial birth abortion"—its asserted interest in the potential

for life and the "severe moral condemnation" for a procedure supposedly resembling infanticide—supersede the state's and the woman's combined interest in preserving her health. See *id.*; contra *Stenberg*, 530 U.S. at 931 ("we cannot see how the interest-related differences *could make any difference* to the question at hand, namely, the application of the 'health' requirement") (emphasis added).

Because the state's interest in potential life has always proved insufficient to overcome the combined interest of the state and the woman in her health, it would be unprecedented and illogical to allow the novel government interest asserted here to surpass the health interests. Even if the Court were willing to consider taking the fateful step of concluding that some interest could overcome the combined interest in women's health, this would be a particularly poor occasion to do so. As noted above, the newly asserted government interest is of a purely moral dimension; the structure of even a narrowly drawn and clearly worded ban—which this is not—would only incidentally affect the number of abortions performed. Such a ban would be certain to channel at least some women into undergoing riskier abortions. Instead of fundamentally reworking abortion law in this country, this Court should adhere to unbroken years of precedent ensuring that abortion regulations do not undermine the medical community's commitment and ability to protect women's health.

CONCLUSION

For the foregoing reasons, the judgment of the United States Court of Appeals for the Ninth Circuit should be affirmed.

Respectfully submitted,

LORIE A. CHAITEN*
LEAH BARTELT
ROGER BALDWIN FOUNDATION
AMERICAN CIVIL LIBERTIES
UNION OF ILLINOIS
180 N. Michigan Ave.,
Suite 2300
Chicago, IL 60601
(312) 201-9740

CARTER G. PHILLIPS
EAMON P. JOYCE
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000

ROBERT N. HOCHMAN
SIDLEY AUSTIN LLP
One South Dearborn Street
Chicago, IL 60603
(312) 853-2936

Counsel for Amici Curiae

September 20, 2006

* Counsel of Record